ISRCTN14521547 https://doi.org/10.1186/ISRCTN14521547

REVERE Breathe

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
24/04/2017

Overall study status
Completed

Last Edited
08/11/2017

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients who are undergoing major surgery to remove part of the oesophagus (gullet) or stomach are advised to complete deep breathing exercises during their early recovery to reduce the risk of post-operative complications, such as lung infections. These exercises may include the use of a device called an incentive spirometer (a medical device used to help patients improve the functioning of their lungs). The patient breathes in through the device as slowly and as deeply as possible, and then holds their breath for three seconds. At present, these are non-electronic devices that do not record how well or how often the patient uses them, nor gives feedback as to how their lungs are performing. This study is looking at a new device called InspireVR, which has been developed to help patients undertake incentive spirometry. Commercial-off-the-shelf products have been combined with purpose-built software to produce an incentive spirometry-based “game”. InspireVR has been designed to remind patients to complete incentive spirometry, encourage them to perform the exercises correctly and record activity for their clinician to review. The aim of this study is to evaluate the usability of this device.

Who can participate?
Adults who are undergoing major surgery to remove part of the oesophagus (gullet) or stomach.

What does the study involve?
At the start of the study, participants are screened to find out if they are suitable to take part. This involves the research team reviewing medical notes and discussing planned care with doctors and nurses before admission for the operation. Patients are seen by a member of the research team during their visit to the preoperative assessment clinic, who ask if they would like to participate in the study and answer any questions. If the patient would like to talk part, written consent is taken at this point. During the preoperative assessment clinic visit the physiotherapist demonstrates the current device (Spiroball) and new device (InspireVR) used for breathing exercises after the operation. Patients participate in the study for three days after their operation. They are advised to carry out the breathing exercises every hour during the daytime, up to 10 times a day, alternating the device used, Spiroball then Inspire VR, each hour. Each day, a member of the research team interviews the participant about their experience using each device. Some patients are also asked if they would agree to a video recording of their bedspace, for one day of the study. This recording is analysed by the research team to assess the impact of the new device on its surroundings.

What are the possible benefits and risks of participating?
The study may not benefit participants, but the information gained will help the treatment of future patients who undergo this type of surgery. Previous studies using computer games have reported occasional nausea, a bit like travel sickness. This is called cybersickness. Approximately 3-5% of participants will experience this, usually within 5-10 minutes after viewing starts. Symptoms usually subside a few minutes after turning the device off.

Where is the study run from?
1. Queen Elizabeth Hospital (UK)
2. Birmingham Heartlands Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2016 to January 2018

Who is funding the study?
Ministry of Defence - Defence Medical Services (UK)

Who is the main contact?
Dr Charlotte Small
drcharlottesmall@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Charlotte Small

ORCID ID
http://orcid.org/0000-0001-8338-7658

Contact details
Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH
+44 7974 001858
charlotte.small@uhb.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

32850

Study information

Scientific Title
Feasibility of the use of Interactive Technology-enhanced Incentive Spirometry (InspireVR) to reduce post-operative pulmonary complications following elective oesophagectomy and total gastrectomy

Study objectives
The aim of this study is to evaluate the usability of a novel device called InspireVR. InspireVR has been developed using a human-centred design process to help patients undertake incentive spirometry.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 22/02/2017, ref: 16/WM/0458

Study design
Non-randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Device, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Specialty: Critical care, Primary sub-specialty: Critical Care; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs

Interventions
The intervention under investigation is an interactive technology-enhanced incentive spirometry, via a device named InspireVR. This novel device will consist of a mouthpiece, though which the patient inhales (Vitalograph Pneumotrac). This mouthpiece contains a pneumotachograph measuring maximum inspiratory capacity (MIC); the signal from which will be converted a novel, bespoke game via purpose built “midware”. The game will be presented on a touch-screen display device (Windows Notebook), which will be incorporated into a stand to

allow comfortable interaction Those recruited into the study will be advised to attempt incentive spirometry sessions hourly from the morning after their operation (day 1), aiming for 10 sessions per day. Each incentive spirometry session will consist of 10 MIC breaths, with short intervals between to allow recovery if required. The patients will be offered the Spiroball and InspireVR device on an alternating basis for each session of incentive spirometry. If the patient is unable to use the InspireVR device, they will be advised to use the alternative Spiroball device instead. The order of which device is offered first each day will be randomised between patients, and alternate each day. The participants will take part in the trial for their first three post operative days following elective oesophagectomy or total gastrectomy.

Data will be collected daily during the patients' ICU stay, and will consist of:
1. Demographic and Patient technology acceptance at pre-admission clinic
2. Daily record of InspireVR and Spirometry use, reasons for refusal of device usage, significant events, pain during incentive spirometry, evidence of PPC. Usage is recorded automatically by the InspireVR system and manually for the Spiroball by the patient and nursing staff.
3. Modified System Usability Scale (Patients and Staff Users)
4. Video capture and link analysis of activity during one daytime shift
5. Performance during InspireVR game. MIC achieved, levels achieved. Recorded automatically by the InspireVR system
6. Qualitative feedback of patient experience of InspireVR using a semi-structured interview on discharge from critical care. Data will be collected on written proformas and entered into NVivo for thematic analysis
7. Focus group to include all staff user groups – Physiotherapists, nurses, doctors. All those who have cared for patients in the study will be invited. Two from each role will be included in each focus group (six persons in total). This will be undertaken three times at eight week intervals during the trial to maximise recall. Focus groups will be recorded and transcribed for thematic analysis using NVivo.
8. Follow up data – PPCs, and other post operative morbidity (Clavien-Dindo classification), length of critical care unit and hospital stay, survival status on hospital discharge and at 30 days post operatively

Intervention Type
Device

Primary outcome measure
Successful patient usage of the InspireVR. Usage will be defined as the total number of successful attempts (patient able to record a MIC breath) using InspireVR compared with number of successful attempts when using Spiroball (as reported by the patient). Feasibility of the device will be established if the number of successful attempts at incentive spirometry during InspireVR use is equal to or higher than the number of patient-reported successful uses of the Spiroball device. InpsireVR usage will be collected via the device software. Use of Spiroball will be reported by the patient and bedside staff using a paper log.

Secondary outcome measures
1. User (patients) acceptance and experience of the InspireVR device is assessed using a 10 item likert scale, based on the validated System Usability Scale on day 3-4 of trial, following completion of intervention
2. User (physiotherapists and nurses) acceptance and experience of the InspireVR device is assessed using a 10 item likert scale, based on the validated System Usability Scale (Focus group during trial period)
3. Compliance with incentive spirometry. Each session will be recorded by embedded software

within the InspireVR device. Use of the Spiroball will recorded by the patient and on the patient nursing records (current standard practice) daily during intervention.
4. Patient achievement of prespecified targets for MIC on the InspireVR is assessed via InspireVR software daily during intervention
5. Side effects and adverse events whilst using the InspireVR device are collected daily during intervention
6. Pain and discomfort experience during use of InspireVR and Spiroball is assessed using a 0-3 Verbal rating scale at each IS session
7. Therapist/clinical staff (doctor/nurse/physiotherapist) user acceptance and experience is assessed through semi structured interviews and free text comments during the trial period
8. Post-operative pulmonary complications (PPCs) as defined by the PROVE network investigators is collected routinely
9. All cause 30 day morbidity (Clavien-Dindo classification)
10. Critical Care Unit length of stay
11. Hospital length of stay
12. In hospital mortality
13. All cause 30 day mortality

Overall study start date
01/08/2016

Completion date
01/01/2018

Eligibility

Key inclusion criteria
Patient Inclusion criteria:
1. All consecutive patients undergoing elective oesophagectomy and total gastrectomy for cancer treatment on their first post-operative admission to the critical care units (intensive care or high dependency units) at QEHB or BHH
2. Age 18 years and over
3. All genders

Staff Inclusion criteria
All clinical, nursing and physiotherapy staff who have had direct care responsibilities for patients participating in the trial will be invited to participate in the focus groups during the study. Physiotherapists, nursing staff and doctors allocated to care for participants will be identified during the intervention days of the study and approached by the research team.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 25; UK Sample Size: 25

Key exclusion criteria
1. Patient refusal
2. Cognitive impairment preventing patient cooperation with breathing exercises
3. Severe visual impairment, such that the patient is unable to visualise the computer display
4. Post-operative complications necessitating placement of tracheostomy

Date of first enrolment
03/04/2017

Date of final enrolment
03/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green E
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham

Sponsor details

Research Support Group
Aston Webb Building
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 121 414 8165
s.jennings@bham.ac.uk

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence - Defence Medical Services

Results and Publications

Publication and dissemination plan
1. Publication of PhD thesis (Dr C Small), to be completed by November 2018
2. Presentation at local, national and international conferences - Critical Care and post operative enhanced recovery
3. Planned publication in a peer reviewed journal by October 2018

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from drcharlottesmall@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3.2	01/01/2017	24/04/2017	No	Yes

HRA research summary	28/06/2023	No	No